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August 25, 2005

Barbara Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

**Re: Use of Updated Nutrition Labeling Values for Fresh
Pears While Final Nutrition Labeling Rule is Pending**

Dear Dr. Schneeman:

On behalf of our client, the Pear Bureau Northwest (Pear Bureau), this letter requests confirmation that the Food and Drug Administration (FDA) would not object to the use of updated nutrition labeling values for fresh pears while the agency completes its final rule on nutrition labeling for fresh produce. 1/ As the leading marketing organization for the fresh pear industry, 2/ the Pear Bureau has a strong interest in providing the latest nutrient data for pears to U.S. consumers. Pear values presently used in FDA's fresh produce program have long been

1/ See 67 Fed. Reg. 12918 (Mar. 20, 2002)(proposed rule); 70 Fed. Reg. 16995 (Apr. 5, 2005)(reopening of the comment period).

2/ Established in 1931, the Pear Bureau Northwest is a non-profit marketing organization that promotes, advertises and develops markets for fresh pears grown in Oregon and Washington. Oregon and Washington comprise the nation's largest pear producing region, producing approximately 84% of all fresh pears grown in the United States, and more than 94% of all winter pears (non-Bartlett varieties such as Bosc and Anjou). The 1,600 growers and 73 packers and shippers represented by the Pear Bureau Northwest take pride in their ability to produce top-quality fresh *USA Pears* for the world market.

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Dr. Barbara Schneeman
August 25, 2005
Page 2

outdated; however, new and reliable nutrition labeling values for pears are now available, based on data provided by the U.S. Department of Agriculture (USDA) and analyzed using well-established FDA procedures for developing nutrition labeling information.

We believe that the new pear values, which the Pear Bureau submitted to FDA in response to the agency's April 2005 request for comments on the pending rulemaking, will ultimately be acceptable to the agency when the final rule is completed. The Pear Bureau wishes, nonetheless, to seek FDA's views as to whether the agency would object to their use in nutrition labeling provided in point of purchase materials and on fresh pear packaging in the meantime. The promotion of pears with current, substantiated nutrition labeling values will further the objectives of the 2005 *Dietary Guidelines for Americans* and MyPyramid, both of which encourage increased consumption of fruits and vegetables, and therefore, would provide an important public benefit.

I. BACKGROUND—NEED FOR NEW DATA

As one of the twenty most commonly consumed raw fruits, pears are subject to FDA's nutrition labeling program for fresh produce,^{3/} including the FDA-determined nutrition values in Appendix C to 21 C.F.R. Part 101. The current pear values were proposed and finalized in 1991 on the basis of the 1982 edition of the USDA Handbook No. 8-9 (fruits and fruit juices). ^{4/} For some nutrients, such as fiber, Handbook 8-9 provided no data points, meaning that values were extrapolated from other sources. Thus, the pear values currently referenced in FDA's regulations are outdated, and in some cases—notably, fiber, an important nutrient for pears—are without a strong, data-based foundation.

In 2002, FDA proposed to update nutrition labeling values for fruits and vegetables in the fresh produce program. ^{5/} In April of this year, FDA announced that it was reopening the comment period for the rule to allow for additional public input concerning new data, including new USDA data for pears, and updated nutrition labeling values. ^{6/} In response to FDA's request for

^{3/} 21 C.F.R. § 101.45.

^{4/} 56 Fed. Reg. 60880 (Nov. 27, 1991).

^{5/} 67 Fed. Reg. at 12924-12926.

^{6/} 70 Fed. Reg. at 16995-96 (Apr. 4, 2005); Letter from Joanne M. Holden, Nutrient Data Laboratory to FDA Dockets Management Branch (Aug. 1, 2002).

Dr. Barbara Schneeman
August 25, 2005
Page 3

comment, the Pear Bureau submitted a statistical analysis of the new USDA pear data as well as market share data for the tested varieties. This analysis, which followed procedures outlined in FDA guidance for developing nutrition labeling values, ^{7/} supported FDA's proposed revised values for pears of 0 g of total fat, 0 calories from fat, 16 g of sugars, and 0% of the calcium daily value (DV) per serving. The analysis also indicated that the fiber value should be updated to 5 g and total carbohydrate to 26 g per serving, and that all other values remain unchanged. The Pear Bureau comments are attached for your reference.

II. IMMEDIATE USE OF NEW PEAR DATA WILL BENEFIT CONSUMERS

The Pear Bureau appreciates FDA's work to complete the pending rulemaking to update nutrition labeling values for pears and other fruits and vegetables. As a "B list" priority for the Center for Food Safety and Applied Nutrition (CFSAN), however, the final rule is unlikely to publish this fiscal year, and competing issues could further delay publication. Although in many situations enforcement discretion would not be appropriate while a final rule is pending, in this instance, prompt use of updated values will provide a substantial public benefit.

Significantly, immediate use of new pear data will provide the public with current, substantiated nutrition information for pears. As noted above, the current values are based on data collected over twenty years ago. Moreover, for important nutrients like fiber, the existing values are based not on analyses in pears, but upon extrapolation from other commodities. In contrast, the new values are based on more recent and extensive data that specifically reflect the nutrient composition of pears.

^{fat already ok}
In addition, the new values reflect changes in two key nutrients: dietary fiber is now 5 g (not 4 g), and fat is 0 g (not 1 g). Informing consumers of these values would better promote pear consumption, consistent with recommendations in the 2005 *Dietary Guidelines for Americans* and MyPyramid for increased fruit and vegetable consumption. It is noteworthy that the *Dietary Guidelines* explicitly highlight the fiber contribution of fresh pears. ^{8/}

^{7/} FDA Guidance for Industry, *Nutrition Labeling Manual—A Guide for Developing and Using Databases* (Mar. 1998).

^{8/} Dietary Guidelines for Americans 2005, App. B-8, p. 63-64 ("Food Sources of Dietary Fiber").

Dr. Barbara Schneeman

August 25, 2005

Page 4

It is also pertinent that the new values are data-driven and not subject to differing interpretations or revision as the rulemaking process proceeds. Although FDA's preliminary values based on the new USDA data did not include a change in the fiber or total carbohydrate content of pears, this proposal was generated without the market share data the Pear Bureau subsequently provided during the public comment period. Based on the agency's clear guidance and well-established approach for calculating nutrition labeling values, the proposal almost certainly would have included a fiber value of 5 g, had the market share data been available to the agency. We also note that FDA has previously not objected to the use of updated nutrition labeling values pending completion of a final rule in this area. ^{9/}

III. PEAR BUREAU REQUEST

Based on the new USDA data, the compelling public interest in promoting fruit consumption, and the straightforward, data-driven nature of the pear values, the Pear Bureau respectfully requests FDA's confirmation that the agency will not object to the immediate use of new nutrient values for pears. We specifically request FDA's views as to whether the agency would object to the use of the updated pear values in the recent FDA proposal ^{10/} and the related Pear Bureau comments (including updated values for fiber (5 g) and total carbohydrate (26 g)) in nutrition labeling provided for fresh pears pursuant to 21 C.F.R. § 101.45 (e.g., point of sale materials provided by retailers) or § 101.9 (e.g., on fresh pear packages), as applicable. The promotion of pears with current, substantiated nutrition labeling values is not only good science; it will further the objectives of the 2005 *Dietary Guidelines for Americans* and MyPyramid, both of which encourage increased consumption of fruits and vegetables.

^{9/} 67 Fed. Reg. at 12,920 ("FDA has considered whether this updated nutrition labeling information, as proposed, could be used on an interim basis prior to completion of the rulemaking. Because the agency believes that the proposed nutrition labeling values would not be misleading, we do not object to firms using these values prior to issuance of a final rule, provided that the nutrition information is presented in a manner consistent with this proposal. However, firms should be aware that a final rule on this issue may differ from this proposed rule.").

^{10/} 70 Fed. Reg. at 16998.

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Dr. Barbara Schneeman
August 25, 2005
Page 5

Thank you for your consideration of this request. If there are any questions or if additional information would be useful, please do not hesitate to contact us.

Respectfully submitted,



Ann M. Boeckman
Counsel to Pear Bureau, Northwest

Enclosure

cc: Dr. Jeanne Rader
Ms. Mary Brandt



PEAR BUREAU NORTHWEST

0925 5 MAY 10 AIO:02

May 4, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2001N-0548; Food Labeling; Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Reopening of the Comment Period 70 Fed. Reg. 16995 (Apr. 4, 2005)

The Pear Bureau Northwest (Pear Bureau) appreciates this opportunity to submit comments concerning nutrition labeling values for fresh pears. Established in 1931, the Pear Bureau Northwest is a non-profit marketing organization that promotes, advertises and develops markets for fresh pears grown in Oregon and Washington. Oregon and Washington comprise the nation's largest pear producing region, producing approximately 84% of all fresh pears grown in the United States, and more than 94% of all winter pears (non-Bartlett varieties such as Bosc and Anjou). The 1,600 growers and 73 packers and shippers represented by the Pear Bureau Northwest take pride in their ability to produce top-quality fresh *USA Pears* for the world market.

The Pear Bureau has commissioned a statistical analysis of new pear data provided to FDA by the U.S. Department of Agriculture. 1/ This analysis, which takes into account the relative market share for each variety tested, was conducted using procedures outlined in FDA guidance for developing nutrition labeling values. 2/ The results support FDA's proposed values for pears of 0 g of total fat, 0 calories from fat, 16 g of sugars, and 0% of the calcium daily value (DV)

1/ Letter from Joanne M. Holden, Nutrient Data Laboratory to FDA Dockets Management Branch (Aug. 1, 2002).

2/ FDA Guidance for Industry, *Nutrition Labeling Manual—A Guide for Developing and Using Databases* (Mar. 1998).

2001N-0548

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Division of Dockets Management

May 4, 2005

Page 2

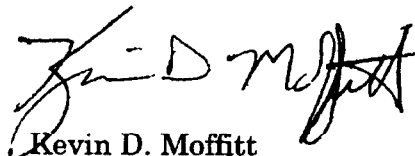
per serving, but indicate that the fiber value should be updated to 5 g and total carbohydrate to 26 g per serving. Copies of the summary report for the statistical analysis, a table of nutrition labeling values indicated, and pertinent market share data are attached.

The Pear Bureau respectfully requests that the nutrition values for pears in Appendix C to 21 C.F.R. Part 101 be updated to reflect the attached analysis. In the interest of providing consumers with updated values as soon as possible, we further request that FDA exercise enforcement discretion and permit use of these values, once confirmed, while the final rule is pending. We note, in this regard, that FDA has previously not objected to the use of updated nutrition labeling values pending completion of a final rule in this area. 3/

* * *

Thank you for your consideration of these comments. If there are any questions concerning this information, please do not hesitate to contact me or our food law counsel, Ann Boeckman of Hogan & Hartson. Ann can be reached at 202-637-5770.

Sincerely,



Kevin D. Moffitt
President and CEO
Pear Bureau Northwest

3/ 67 Fed. Reg. 12,918, 12,920 (Mar. 20, 2002).

Food Research, Inc.

575 Anton Blvd. Suite 300

Costa Mesa, CA 92626

949/497-6066

Nutrient Composition of Fresh Pears Sold in the United States

Summary Report to Pear Bureau Northwest

March 29, 2005

Nutrient Data

For this research, Food Research, Inc. used the USDA data that was submitted to FDA in August, 2002 (comment on Proposed Amendments to Guidelines for Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish, Docket No. 01N-0548).

Four varieties of pears were collected from four U.S. regions in a market-basket sampling, as part of USDA's National Food and Nutrient Analysis Program (NFNAP). We contacted USDA to obtain the sample collection dates, which were October 2000 and May 2001.

Sample Weighting

There are an equal number of data points for each of the four varieties tested: Bartlett, Bosc, Green Anjou and Red Anjou. Because these varieties do not have equal market shares, we weighted the data according to the market share of each variety.

Pear Bureau Northwest provided the 2004 market share information for fresh pears sold in the U.S., including domestically-grown and imported. The source of the market share data is the Winter Pear Control Committee, the Federal Marketing Order for fresh pears grown in Oregon and Washington.

The four pear varieties that were tested represent approximately 85% of all fresh market pears sold in the U.S. We weighted the data according to the market share (metric tons) of each variety as follows: Bartlett 189,278, Bosc 88,065, Green Anjou 143,944 and Red Anjou 12,278.

Nutrition Labeling

We converted the weighted nutrient data to the FDA serving size of 166 grams (1 medium pear) and applied FDA nutrition labeling statistics, calculating the 95% prediction interval (PI) for each nutrient and then selecting the mean or PI, as appropriate, for the nutrition labeling value.

Table 1 summarizes the results of the statistical analysis and nutrition labeling values that are indicated by the analysis. For each nutrient, the table shows: number of data points (n), weighted mean, weighted standard deviation (SD), weighted 95% prediction interval value (PI), minimum and maximum value, rounded nutrition label value, and the basis for the label value (e.g., mean and/or PI). Percent Daily Values (% DV) are also shown for each nutrient for which a Daily Value has been established.

All of the results for carotenes (beta carotene, alpha carotene and beta cryptoxanthin) indicate a nutrition labeling value of zero for vitamin A. No data were provided for sodium, potassium, or vitamin C.

Table 1

**Pears: Weighted Nutrition Labeling Statistics
USDA Nutrient Data for 4 Varieties
166-gram Serving**

Nutrient	Unit	n	Mean	Mean %DV	SD	95% PI	95% PI %DV	Low	Low %DV	High	High %DV	Rounded Label	Rounded Label %DV	Label Basis
Calories	kcal	24	96.23		4.14	86.23		88.42		109.80		100		Mean
Fat Calories	kcal	24	1.75		1.00	2.91		0.14		4.17		0		PI & Mean
Fat	g	24	0.21	0.32%	0.12	0.35	0.54%	0.02	0.03%	0.50	0.77%	0	0%	PI & Mean
Carb	g	24	25.64	8.55%	1.17	29.49	9.83%	23.66	7.89%	29.52	9.84%	26	9%	Mean
Fiber	g	24	5.80	23.18%	1.10	4.84	19.37%	4.19	16.75%	7.44	29.76%	5	20%	PI
Sugars	g	24	16.28		1.44	15.66		14.07		19.57		16		PI & Mean
Protein	g	24	0.65		0.15	0.48		0.39		0.98		< 1		PI & Mean
Calcium	mg	16	9.96	1.00%	6.84	0.00	0.00%	6.49	0.65%	21.41	2.14%		0%	PI & Mean
Iron	mg	16	0.22	1.20%	0.22	0.00	0.00%	0.13	0.70%	0.93	5.19%		0%	PI

USA Pear Production and imports (2-05)

	<u>Fresh USA Grown Pears Sold Domestically</u>	<u>Fresh Imported Pears Sold Domestically</u>	<u>Total Fresh Pears Sold Domestically</u>	<u>Percent of Total</u>
Anjou	131,000	12,944	143,944	28%
Bartletts	105,000	84,278	189,278	37%
Bosc	55,287	32,778	88,065	17%
Red Anjou	11,000	1,278	12,278	2%
Comice	4,950	0	4,950	1%
Seckel	960	0	960	0%
Other Reds	975	3,962	4,937	1%
Other Varieties	1,215	8,278	9,493	2%
Packham	0	56,222	56,222	11%
Total Fresh Pears	310,387	199,740	510,127	

**the data in this chart represents only the domestic US marketplace, the data below contains total market information for bartletts.*

USA Bartlett Pear Production

Currently Bartlett pears are the only variety used in processing in any major way

	<u>Yearly Average Tonnage</u>
Processed Bartlett	297,862
Fresh Bartlett	<u>126,698</u>
Total Bartlett	424,560
Percent of Bartlett tonnage	
Processed	70%

Data expressed in Metric tons (2200 lbs)

data source: Winter Pear Control Committee, Northwest Fresh Bartlett Marketing Committee,
Oregon Bartlett Pear Commission